Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Page: 193

Report Date:11/17/2008

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
				Ma	ale		
Battelle Columbus Laboratory Southern Research Institute Battelle Columbus Laboratory Southern Research Institute Southern Research Institute Southern Research Institute	058813803 059902703 050517405 059900705 059201305 052000803	08/16/99 08/12/02 08/05/02 04/21/03 01/20/00 03/04/03	729 729 729 729 730 729	50 (3) 50 (3) 50 (3) 50 (3) 50 (3) 50 (3)	22(681) 37(705) 33(703) 33(679) 31(702) 36(704)	501.7 452.8 510.0 460.9 448.0 452.1	Benzophenone Chromium picolinate monohydrate Cresols Goldenseal root powder 4-Methylimidazole Milk thistle extract
				Fen	nale		
Battelle Columbus Laboratory Southern Research Institute Battelle Columbus Laboratory Southern Research Institute Southern Research Institute Southern Research Institute	058813803 059902703 050517405 059900705 059201305 052000803	08/17/99 08/12/02 N/A 04/21/03 01/20/00 03/04/03	729 733 N/A 731 735 732	50 (5) 50 (5) 0 (0) 50 (5) 50 (5) 50 (5)	32(688) 36(702) 0(0) 30(699) 40(702) 38(693)	348.7 314.7 N/A 326.0 311.3 328.4	Benzophenone Chromium picolinate monohydrate Cresols Goldenseal root powder 4-Methylimidazole Milk thistle extract

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Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 194

			Male				Female	
All Organs: Benign Tumors								
Benign rumors		49/50 (98%)	49/50 (98%)	50/50 (100%)		42/50 (84%)	45/50 (90%)	
		47/50 (94%)	50/50 (100%)	50/50 (100%)		46/50 (92%)	48/50 (96%)	39/50 (78%)
overall Incidence	Total	295/300 (98.33%)	Mean 98.33%	SD 2.34%	Total	220/250 (88%)	Mean 88%	SD 7.07%
All Organs: Malignant Tumors			•••••	•••••				
		33/50 (66%)	27/50 (54%)	23/50 (46%)		20/50 (40%)	15/50 (30%)	10/70 (000)
	-	29/50 (58%)	22/50 (44%)	26/50 (52%)	-	19/50 (38%)	19/50 (38%)	18/50 (36%)
Overall Incidence	Total	160/300 (53.33%)	Mean 53.33%	SD 8.07%	Total	91/250 (36.4%)	Mean 36.4%	SD 3.85%
#All Organs: Malignant and Benign T	umors							
		50/50 (100%)	50/50 (100%)	50/50 (100%)		46/50 (92%)	47/50 (94%)	10/50 (000()
S	T-1-1	50/50 (100%)	50/50 (100%)	50/50 (100%)	T-1-1	48/50 (96%)	48/50 (96%)	46/50 (92%)
Overall Incidence	Total	300/300 (100%)	Mean 100%	SD 0%	Total	235/250 (94%)	Mean 94%	SD 2%
All Organs: Hemangioma								
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%
All Organs: Hemangiosarcoma								
		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (001)
S	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.63%	Total	0/250 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 195 Report Date:11/17/2008

Species: RATS Strain: F344 Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
All Organs: Hemangiosarcoma or He	emangioma							
Tromangrood coma or tro	, mangioma	0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	3/300 (1%)	Mean 1%	SD 1.67%	Total	0/250 (0%)	Mean 0%	SD 0%
All Organs: Histiocytic Sarcoma							•••••	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/20 (00/)
	T-1-1	0/50 (0%)	0/50 (0%)	3/50 (6%)	T-1-1	1/50 (2%)	2/50 (4%)	0/50 (0%)
verall Incidence	Total	3/300 (1%)	Mean 1%	SD 2.45%	Total	4/250 (1.6%)	Mean 1.6%	SD 1.67%
All Organs: Leukemia: Erythrocytic								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	4/50 (00/)
verall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0.4%	1/50 (2%) SD 0.89%
veran incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	wean 0.4%	SD 0.69%
All Organs: Leukemia: Lymphocytic Undifferentiated	, Monocytic, N	lononuclear, or						
		27/50 (54%)	19/50 (38%)	15/50 (30%)		19/50 (38%)	9/50 (18%)	
		21/50 (42%)	15/50 (30%)	17/50 (34%)		9/50 (18%)	9/50 (18%)	6/50 (12%)
verall Incidence	Total	114/300 (38%)	Mean 38%	SD 9.12%	Total	52/250 (20.8%)	Mean 20.8%	SD 9.96%
All Organs: Malignant Lymphoma: H or Undifferentiated Cell		nphocytic, Mixed, NOS,	,					
or oriumerentiated cen	i ype	0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	
			0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/30 (0%)		0/30 (0/0)	0/30 (0/0)	0/30 (0/0)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: RATS

Strain: F344 Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Report Date:11/17/2008

Page: 196

			Male				Female	
#All Organs: Mesothelioma: Benign								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#All Organs:								
Mesothelioma: Benign, Ma	lignant, NO	5 2/50 (4%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/300 (1%)	Mean 1%	SD 1.67%	Total	0/250 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Malignant								
3		2/50 (4%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/300 (1%)	Mean 1%	SD 1.67%	Total	0/250 (0%)	Mean 0%	SD 0%
fAll Organs: Osteoma					•••••			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%
All Organs: Osteosarcoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	3/300 (1%)	Mean 1%	SD 1.67%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 197

			Male		Female	
All Organs: Osteosarcoma or Osteoma						
		1/50 (2%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	
		2/50 (4%)	0/50 (0%) 1/50	(2%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
verall Incidence	Total	4/300 (1.33%)		.63% Total	1/250 (0.4%) Mean 0.4%	SD 0.89%
Adrenal Cortex: Adenoma						
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 2/50 (4%)	2/12 /22/
		0/50 (0%)	1/50 (2%) 2/50	(4%)	1/50 (2%) 1/49 (2%)	0/48 (0%)
Overall Incidence	Total	3/300 (1%)	Mean 1% SD 1	.67% Total	4/247 (1.62%) Mean 1.61%	SD 1.68%
Adrenal Cortex: Carcinoma						
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/49 (0%)	0/48 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0% SD 0		0/247 (0%) Mean 0%	SD 0%
Adrenal Medulla: Ganglioneuroma						
_		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	
		0/49 (0%)	0/50 (0%) 0/50	(0%)	0/48 (0%) 0/48 (0%)	0/48 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0% SD 0		0/244 (0%) Mean 0%	SD 0%
Adrenal Medulla: Hemangioma						
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/40 (00/)
Normall Implidance	Tatal	0/49 (0%)	0/50 (0%) 0/50	(0%)	0/48 (0%) 0/48 (0%)	0/48 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0% SD 0	% Total	0/244 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 198

			Male				Female	
Adrenal Medulla: Pheochromocytoma Be	enian							
Fileociiromocytoma Be	enign	8/50 (16%)	8/50 (16%)	8/50 (16%)		0/50 (0%)	1/50 (2%)	
		5/49 (10%)	8/50 (16%)	5/50 (10%)		0/48 (0%)	2/48 (4%)	1/48 (2%)
Overall Incidence	Total	42/299 (14.05%)	Mean 14.03%	SD 3.05%	Total	4/244 (1.64%)	Mean 1.65%	SD 1.74%
Adrenal Medulla: Pheochromocytoma Co	omplex					•••••		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/49 (0%)	2/50 (4%)	1/50 (2%)		0/48 (0%)	0/48 (0%)	1/48 (2%)
Overall Incidence	Total	3/299 (1%)	Mean 1%	SD 1.67%	Total	1/244 (0.41%)	Mean 0.42%	SD 0.93%
Adrenal Medulla: Pheochromocytoma M	alignant		•••••			•••••	•••••	
		0/50 (0%)	3/50 (6%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	2/12 (22/)
		1/49 (2%)	0/50 (0%)	0/50 (0%)		0/48 (0%)	1/48 (2%)	0/48 (0%)
verall Incidence	Total	4/299 (1.34%)	Mean 1.34%	SD 2.42%	Total	3/244 (1.23%)	Mean 1.22%	SD 1.8%
Adrenal Medulla:								
Pheochromocytoma: B	senign, Complex	8/50 (16%)	11/50 (22%)	8/50 (16%)		0/50 (0%)	3/50 (6%)	
		6/49 (12%)	10/50 (22%)	6/50 (12%)		0/30 (0%)	3/48 (6%)	2/48 (4%)
verall Incidence	Total	49/299 (16.39%)	Mean 16.37%	SD 4.03%	Total	8/244 (3.28%)	Mean 3.28%	SD 3.1%
Bone: Chondrosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
	_	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 199

			Male		Female
Bone: Chondrosarcoma or Chondr	oma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	` ,	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0% SD 0%	Total 0/250 (0%)	Mean 0% SD 0%
Bone: Chordoma					
		1/50 (2%)	0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	3/300 (1%)	Mean 1% SD 1.1%	Total 0/250 (0%)	Mean 0% SD 0%
#Bone: Osteoma					
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33% SD 0.82%	,	Mean 0% SD 0%
#Bone: Osteosarcoma					
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%) 0/50 (0%)
overall Incidence	Total	2/300 (0.67%)	Mean 0.67% SD 1.63%	Total 1/250 (0.4%)	Mean 0.4% SD 0.89%
#Bone: Osteosarcoma or Osteoma					
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
S	T-1-1	2/50 (4%)	0/50 (0%) 1/50 (2%)	0/50 (0%)	1/50 (2%) 0/50 (0%)
Overall Incidence	Total	3/300 (1%)	Mean 1% SD 1.67%	Total 1/250 (0.4%)	Mean 0.4% SD 0.89%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 200

			Male		Female	
Brain: Astrocytoma Malignant						
Astrooytoma mangnant		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	
		0/49 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0% SD		0/250 (0%) Mean 0%	SD 0%
Brain: Ependymoma Benign						•
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	
		0/49 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0% SD	0% Total	0/250 (0%) Mean 0%	SD 0%
Brain: Ependymoma Malignant						
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	
		1/49 (2%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.34% SD	0.83% Total	0/250 (0%) Mean 0%	SD 0%
Brain: Glioma Malignant						•••••
Guoma mangnam		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	
		0/49 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0% SD	0% Total	0/250 (0%) Mean 0%	SD 0%
Brain: Granular Cell Tumor Benign						
		0/50 (0%)	2/50 (4%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/=0 (00/)
	.	0/49 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67% SD	1.63% Total	0/250 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F344

on: NOV2008

Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 201

			Male				Female	
Brain: Medulloblastoma Mal		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
overall Incidence	Total	0/49 (0%) 0/299 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Brain: Meningioma Malignant								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		2.200 (0,0)						
Brain: Meningioma: Benign, Mal	ignant, NOS							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	2 (22 (22 (22 (22 (22 (22 (22 (22 (22 (
Overall Incidence	Total	0/49 (0%) 0/299 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		0,200 (0,0)	Modif 070			0,200 (0,0)	Moun 070	02 070
Brain: Oligodendroglioma Benig	ın							
3 3 4 4 5	•	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Brain: Oligodendroglioma Malig		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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Contract/Lab: All Laboratories **Species:** RATS

Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 202

			Male				Female	
Brain:								
Oligodendroglioma, Gli	oma, or Astroc	ytoma 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/30 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
					• • • • • • • • • • • • • • • • • • • •			•••••
Brain: Osteosarcoma								
Osteosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Brain: Schwannoma Malignan	t							
3		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland:						•••••		
Adenoma		0/50 (00/)	1/50 (20/)	E/EO (400/)		2/50 (60/)	40/50 (200/)	
		0/50 (0%) 0/50 (0%)	1/50 (2%) 2/50 (4%)	5/50 (10%) 1/50 (2%)		3/50 (6%) 5/50 (10%)	10/50 (20%) 8/50 (16%)	11/50 (22%)
Overall Incidence	Total	9/300 (3%)	Mean 3%	SD 3.74%	Total	37/250 (14.8%)	Mean 14.8%	SD 6.72%
		` ,				` ,		
Clitoral/Preputial Gland: Carcinoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	
		2/50 (4%)	0/50 (0%)	2/50 (4%)		4/50 (8%)	2/50 (4%)	3/50 (6%)
Overall Incidence	Total	5/300 (1.67%)	Mean 1.67%	SD 1.97%	Total	10/250 (4%)	Mean 4%	SD 3.16%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 203

			Male				Female	
Clitoral/Preputial Gland: Carcinoma or Adenoma								
		1/50 (2%)	1/50 (2%)	5/50 (10%)		4/50 (8%)	10/50 (20%)	
		2/50 (4%)	2/50 (4%)	3/50 (6%)		9/50 (18%)	10/50 (20%)	14/50 (28%)
verall Incidence	Total	14/300 (4.67%)	Mean 4.67%	SD 3.01%	Total	47/250 (18.8%)	Mean 18.8%	SD 7.16%
Clitoral/Preputial Gland: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	2/52 (22/)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Squamous Cell Papilloma								
- -		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Ear: Neural Crest Tumor								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/250 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Werall illustrate	i olai	0/300 (0%)	IVICALI U70	3D 0%	ı Olai	0/230 (0%)	IVICALI U%	3D 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Report Date:11/17/2008

Page: 204

Species: RATS Strain: F344

Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
Esophagus: Fibrosarcoma								
i ibi osai coma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
sophagus: Lipoma						•••••		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Eye: Amelanotic Melanoma, E	3enign							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Eye: Melanoma Benign								
3		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Eye: Melanoma Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 205

			Male				Female	
Eye:								
Schwannoma Malignant		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%
Harderian Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Harderian Gland: Carcinoma or Adenoma			•••••			•••••		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Heart: Schwannoma Benign			•••••			•••••		
John Marine Domign		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Heart: Schwannoma Malignant								
		1/50 (2%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (00/)
Normall Institutes	Tatal	0/50 (0%)	0/50 (0%)	1/50 (2%)	Tatal	1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/300 (1%)	Mean 1%	SD 1.1%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/17/2008

Page: 206

Species: RATS Strain: F344 Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male	Female
Intestine Large: Colon/Red Adenoma	ctum:			
		0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33% SD 0.82%	Total 0/250 (0%) Mean 0% SD 0%
Intestine Large: Colon/Red Carcinoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0% SD 0%	Total 0/250 (0%) Mean 0% SD 0%
Intestine Large: Colon/Red Carcinoma or Adenoma				
		0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33% SD 0.82%	Total 0/250 (0%) Mean 0% SD 0%
Intestine Large: Colon/Red Hemangioma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33% SD 0.82%	Total 0/250 (0%) Mean 0% SD 0%
Intestine Small: Duodenur Carcinoma				
		0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
	-	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33% SD 0.82%	Total 0/250 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
#Intestine Small: Duodenum: Leiomyoma								
,		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
	•••••	•••••						
#Intestine Small: Jejunum: Carcinoma							- / / / / / / / / / /	
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/250 (0%)	0/30 (0%) Mean 0%	SD 0%
Overall incidence	TOlai	0/300 (0%)	Mean 0%	3D 0%	Total	0/250 (0%)	Mean 0%	3D 0%
#Intestine Small: Jejunum: Granular Cell Tumor Malig	ınant		•••••					
	,	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyoma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total		0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Overall incluence	Total	0/300 (0%)	iviean 0%	30 0%	I Ulai	0/250 (0%)	Weari 0%	30 0%
#Intestine Small: Jejunum: Leiomyosarcoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/.)	0/50 (00/)	
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/250 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Overall illelucites	i otai	0/300 (0/0)	IVICALI U/0	3D 0/0	iolai	0/200 (0/0)	IVICALI U/0	30 0/0

^{*:} Denominator is number of animals with tissues examined microscopically

Page: 207

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 208

			Male				Female						
#Intestine Small: Site Unspecified: Carcinoma													
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)					
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%					
Intestine Small: Site Uns Carcinoma or Adenom					•••••		•••••						
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (004)					
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%					
fintestine Small: Site Uns Granular Cell Tumor N													
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)					
	-	0/50 (0%)	0/50 (0%)	0/50 (0%)	-	0/50 (0%)	0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%					
fIntestine Small: Site Uns Leiomyoma	pecified:												
,		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)					
overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%					
Intestine Small: Site Uns Leiomyosarcoma													
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (001)					
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%					

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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Contract/Lab: All Laboratories Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 209

			Male				Female	
Islets, Pancreatic: Adenoma								
		1/50 (2%)	1/50 (2%)	1/49 (2%)		0/50 (0%)	2/49 (4%)	0/40 (00/)
Second Head days	T-1-1	7/50 (14%)	3/50 (6%)	3/50 (6%)	T-1-1	0/49 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	16/299 (5.35%)	Mean 5.34%	SD 4.67%	Total	2/245 (0.82%)	Mean 0.82%	SD 1.83%
Islets, Pancreatic: Carcinoma								
		0/50 (0%)	1/50 (2%)	1/49 (2%)		0/50 (0%)	0/49 (0%)	2/12 (22/)
	-	0/50 (0%)	0/50 (0%)	1/50 (2%)	-	0/49 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	3/299 (1%)	Mean 1.01%	SD 1.1%	Total	0/245 (0%)	Mean 0%	SD 0%
Islets, Pancreatic: Carcinoma or Adenoma						•••••		
		1/50 (2%)	2/50 (4%)	2/49 (4%)		0/50 (0%)	2/49 (4%)	
		7/50 (14%)	3/50 (6%)	4/50 (8%)		0/49 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	19/299 (6.35%)	Mean 6.35%	SD 4.27%	Total	2/245 (0.82%)	Mean 0.82%	SD 1.83%
Kidney: Pelvis and Transition Carcinoma						•••••	•••••	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	
		1/50 (2%)	0/48 (0%)	0/50 (0%)		0/49 (0%)	0/48 (0%)	0/48 (0%)
verall Incidence	Total	1/298 (0.34%)	Mean 0.33%	SD 0.82%	Total	0/242 (0%)	Mean 0%	SD 0%
Kidney: Pelvis and Transition Carcinoma or Adenoma		m:						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	2442 (221)
		1/50 (2%)	0/48 (0%)	0/50 (0%)		0/49 (0%)	0/48 (0%)	0/48 (0%)
Overall Incidence	Total	1/298 (0.34%)	Mean 0.33%	SD 0.82%	Total	0/242 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 210

			Male				Female	
Kidney: Pelvis and Transition Papilloma	al Epitheliui	m:						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	
		0/50 (0%)	0/48 (0%)	0/50 (0%)		0/49 (0%)	1/48 (2%)	0/48 (0%)
verall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	1/242 (0.41%)	Mean 0.42%	SD 0.93%
Kidney: Renal Tubule: Adenoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	2/12 (22/)
		0/50 (0%)	0/48 (0%)	0/50 (0%)		0/49 (0%)	0/48 (0%)	0/48 (0%)
Overall Incidence	Total	1/298 (0.34%)	Mean 0.33%	SD 0.82%	Total	0/242 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	
		0/50 (0%)	0/48 (0%)	0/50 (0%)		0/49 (0%)	0/48 (0%)	0/48 (0%)
verall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/242 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma or Adenoma			•••••					
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	
		0/50 (0%)	0/48 (0%)	0/50 (0%)		0/49 (0%)	0/48 (0%)	0/48 (0%)
verall Incidence	Total	1/298 (0.34%)	Mean 0.33%	SD 0.82%	Total	0/242 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	0/40 (00/)
Novell Incidence	Total	0/50 (0%)	0/48 (0%)	0/50 (0%)	Total	0/49 (0%)	0/48 (0%)	0/48 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/242 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 211

			Male	Female
*Kidney: Renal Tubule: Lipoma		0/50 (00/)	0/50 (00/)	0/50 (00) 0/47 (00)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/48 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0% SD 0%	Total 0/242 (0%) Mean 0% SD 0%
*Kidney: Renal Tubule: Liposarcoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/48 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/298 (0%)	0/48 (0%) 0/50 (0%) Mean 0% SD 0%	Total 0/242 (0%)
Overall incluence	Total	0/200 (0/0)	Wedit 070	10tal 0/242 (0/0) Wican 0/0 GD 0/0
*Kidney: Renal Tubule: Mesenchymal Tumor Benign				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/47 (0%)
Overall Incidence	Total	0/50 (0%) 0/298 (0%)	0/48 (0%) 0/50 (0%) Mean 0% SD 0%	0/49 (0%) 0/48 (0%) 0/48 (0%) Total 0/242 (0%) Mean 0% SD 0%
		,		
*Kidney: Renal Tubule: Nephroblastoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/48 (0%) 0/50 (0%)	0/50 (0%) 0/47 (0%) 0/49 (0%) 0/48 (0%) 0/48 (0%)
Overall Incidence	Total	0/50 (0%)	0/48 (0%) 0/50 (0%) Mean 0% SD 0%	0/49 (0%) 0/48 (0%) 0/48 (0%) Total 0/242 (0%) Mean 0% SD 0%
		,	Wedit 070	10tal 0/242 (0/0) Wican 0/0 05 0/0
*Kidney: Renal Tubule: Sarcoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/47 (0%)
Overall Incidence	Total	0/50 (0%)	1/48 (2%) 0/50 (0%) Mean 0.35% SD 0.85%	1/49 (2%) 0/48 (0%) 0/48 (0%) Total 1/242 (0.41%) Mean 0.41% SD 0.91%
Overall incluence	Total	1/298 (0.34%)	Weatt 0.33% 3D 0.03%	Total 1/242 (0.41%) Mean 0.41% SD 0.91%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 212

			Male		Female
Liver:					
Cholangioma		0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
overall Incidence	Total	2/300 (0.67%)	Mean 0.67% SD 1.03%	Total 0/250 (0%)	Mean 0% SD 0%
Liver:					
Hemangiosarcoma		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0% SD 0%	Total 0/250 (0%)	Mean 0% SD 0%
Liver: Hepatocellular Adenoma					
		2/50 (4%)	1/50 (2%) 0/50 (0%)	0/50 (0%)	2/50 (4%)
		1/50 (2%)	0/50 (0%) 3/50 (6%)	0/50 (0%)	0/50 (0%) 2/50 (4%)
Overall Incidence	Total	7/300 (2.33%)	Mean 2.33% SD 2.34%	Total 4/250 (1.6%)	Mean 1.6% SD 2.19%
Liver:					
Hepatocellular Carcinoma		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0% SD 0%	Total 0/250 (0%)	Mean 0% SD 0%
Liver: Hepatocellular Carcinoma c					
riepatocenulai Carcillollia C	n nepatob	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0% SD 0%	Total 0/250 (0%)	Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F344

Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 213

			Male				Female	
Liver:								
Hepatocellular Carcinon	na or Hepatoce		(00)	0/=0 (00/)		0/=0 (00/)	0.700 (404)	
		2/50 (4%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	0/50 (40/)
	-	1/50 (2%)	0/50 (0%)	3/50 (6%)	-	0/50 (0%)	0/50 (0%)	2/50 (4%)
verall Incidence	Total	7/300 (2.33%)	Mean 2.33%	SD 2.34%	Total	4/250 (1.6%)	Mean 1.6%	SD 2.19%
_iver:			•••••	•••••		•••••		
Hepatocellular Carcinon Hepatoblastoma	na, Hepatocell	ular Adenoma, or						
Пераговіазгоніа		2/50 (4%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	
		1/50 (2%)	0/50 (0%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	7/300 (2.33%)	Mean 2.33%	SD 2.34%	Total	4/250 (1.6%)	Mean 1.6%	SD 2.19%
Lung: Alveolar/Bronchiolar Ad	enoma							
7.1.100.101.7 E.		4/50 (8%)	0/50 (0%)	1/50 (2%)		4/50 (8%)	1/50 (2%)	
		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	6/300 (2%)	Mean 2%	SD 3.1%	Total	6/250 (2.4%)	Mean 2.4%	SD 3.29%
Lung:	•••••					• • • • • • • • • • • • • • • • • • • •		
Alveolar/Bronchiolar Ca	rcinoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Lung:	•••••							
Alveolar/Bronchiolar Ca	rcinoma or Alv	veolar/Bronchiolar						
Adenoma		4/50 (8%)	0/50 (0%)	1/50 (2%)		4/50 (8%)	1/50 (2%)	
		4/50 (8%) 1/50 (2%)	0/50 (0%)	1/50 (2%)		4/50 (8%) 1/50 (2%)	0/50 (2%)	1/50 (2%)
Overall Incidence	Total	7/300 (2.33%)	Mean 2.33%	SD 2.94%		7/250 (2.8%)	Mean 2.8%	SD 3.03%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: RATS

Strain: F344 Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 214

			Male	Female
*Lung: Hemangiosarcoma		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/250 (0%) Mean 0% SD 0%
*Lung: Sarcoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0% SD 0%	Total 0/250 (0%) Mean 0% SD 0%
*Lung: Squamous Cell Carcinoma				
·		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33% SD 0.82%	Total 0/250 (0%) Mean 0% SD 0%
#Lymph Node: Hemangiosarcoma			0/50 (0%)	
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0% SD 0%	Total 0/250 (0%) Mean 0% SD 0%
#Lymph Node, Mesenteric: Sarcoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0% SD 0%	Total 0/250 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS Strain: F344

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 215

			Male				Female	
Mammary Gland: Adenoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		2/50 (4%)	1/50 (2%)	0/50 (00/)
	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	2/50 (4%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	5/250 (2%)	Mean 2%	SD 2%
Mammary Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	4/50 (00/)
	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	4/50 (8%)	2/50 (4%)	4/50 (8%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	10/250 (4%)	Mean 4%	SD 4%
Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		2/50 (4%)	1/50 (2%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		6/50 (12%)	2/50 (4%)	4/50 (8%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	15/250 (6%)	Mean 6%	SD 4%
Mammary Gland: Fibroadenoma								
1 101 0 0 0 0 1 1 1 1 1 1 1 1 1 1 1 1 1		2/50 (4%)	2/50 (4%)	0/50 (0%)		27/50 (54%)	29/50 (58%)	
		1/50 (2%)	3/50 (6%)	0/50 (0%)		30/50 (60%)	24/50 (48%)	28/50 (56%)
verall Incidence	Total	8/300 (2.67%)	Mean 2.67%	SD 2.42%	Total	138/250 (55.2%)	Mean 55.2%	SD 4.6%
Mammary Gland: Fibroma	•••••				•••••			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
Normall In all Invan	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 216

			Male				Female	
Mammary Gland:								
Fibroma, Fibroadenom	na or Adenoma	0/50 (404)	0/50 (40/)	4/50 (00/)		00/50 (500/)	00/50 (000/)	
		2/50 (4%)	2/50 (4%)	1/50 (2%)		28/50 (56%)	30/50 (60%)	00/50 /500/
	-	1/50 (2%)	3/50 (6%)	0/50 (0%)	.	30/50 (60%)	24/50 (48%)	28/50 (56%)
verall Incidence	Total	9/300 (3%)	Mean 3%	SD 2.1%	Total	140/250 (56%)	Mean 56%	SD 4.9%
Mammary Gland:								
Fibroma, Fibroadenom	na, Carcinoma, o	or Adenoma						
		2/50 (4%)	2/50 (4%)	1/50 (2%)		28/50 (56%)	30/50 (60%)	00/00 /05::
		1/50 (2%)	3/50 (6%)	0/50 (0%)		31/50 (62%)	25/50 (50%)	28/50 (56%)
verall Incidence	Total	9/300 (3%)	Mean 3%	SD 2.1%	Total	142/250 (56.8%)	Mean 56.8%	SD 4.6%
Mesentery: Fibrosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Hemangiosarcoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%
Mesentery: Lipoma					•••••			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 217

			Male				Female	
Mesentery: Rhabdomyosarcoma		(201)	2/72 (221)			2/22 (22)	2/72 (201)	
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/	50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	\ /	SD 0%
Nose: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	50 (00()
Overall Incidence	Total	0/50 (0%)	0/49 (0%)	0/50 (0%) SD 0%	Total	0/50 (0%)	0/49 (0%) 0/	` '
verali incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)	Mean 0%	SD 0%
Nose: Chondroma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	(224)
Normall In all Invan	T-1-1	0/50 (0%)	0/49 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/49 (0%) 0/	(/
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)		SD 0%
Nose: Squamous Cell Carcinoma								
.,		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	(/	50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)	Mean 0%	SD 0%
					•••••			
Oral Cavity (Oral Mucosa, Tong Papilloma Squamous or Pap		nx, Tooth, Gingiva):						
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
	-	1/50 (2%)	0/50 (0%)	1/50 (2%)	.	1/50 (2%)	0/50 (0%) 0/	` '
Overall Incidence	Total	4/300 (1.33%)	Mean 1.33%	SD 1.03%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Vehicle: FEED

Animal Groups Report Date:11/17/2008

Page: 218

Species: RATS Strain: F344

Length of Study: CHRONIC

			Male				Female	
#Oral Cavity (Oral Mucosa, Squamous Cell Carcino		nx, Tooth, Gingiva):						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%
	• • • • • • • • • • • • • • • • • • • •	•••••		•••••	• • • • • • • • • • • • • • • • • • • •	•••••	•••••	•••••
#Oral Cavity (Oral Mucosa, Squamous Cell Carcino Papilloma								
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		2/50 (4%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	5/300 (1.67%)	Mean 1.67%	SD 1.51%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Oral Mucosa: Squamous Cell Carcino	ma	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	•••••	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%
#Oral Mucosa: Squamous Cell Papillon	na	0/50 (00/)	0/50 (00/)	0/50 (00/)		0(50 (00))	0/50 (00/)	
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
	. 0.01	2.300 (0.0)				2.200 (070)		32 0,0
*Ovary: Granulosa Cell Tumor B	Benian							
	· - · · · ɔ · ·					0/50 (0%)	0/50 (0%)	0/50 (00/)
Overall Incidence					Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 219

	Male			Female	
Ovary:					
Granulosa Cell Tumor Malignant		0/50	(0%)	0/50 (0%)	
		0/50		0/50 (0%)	2/50 (4%)
Overall Incidence	Total	2/250	(0.8%)	Mean 0.8%	SD 1.79%
_		• • • • • • • • • • • • • • • • • • • •	• • • • • • • • • • • • • • • • • • • •		
Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS					
Grandiosa sen ramor. Benign, manghant, 1100		0/50	(0%)	0/50 (0%)	
		0/50	(0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	2/250	(0.8%)	Mean 0.8%	SD 1.79%
Ovary:		•••••	•••••		
Granulosa-Theca Tumor Benign		0/50	(00()	4/50 (00/)	
		0/50 0/50		1/50 (2%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total		(0.4%)	Mean 0.4%	SD 0.89%
Ovary:					• • • • • • • • • • • • • • • • • • • •
Granulosa-Theca Tumor Malignant					
		0/50		0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/50	()	0/50 (0%)	0/50 (0%) SD 0%
verali incidence	Total	0/250	,	Mean 0%	
Ovary:					
Tubulostromal Adenoma		0/50	(00()	0/50 (00/)	
		0/50 0/50		0/50 (0%) 0/50 (0%)	0/50 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F344

Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 220

			Male		Female
Pancreas: Adenoma					
		0/50 (0%)	0/49 (0%) 0/49 (0		0/49 (0%)
		0/50 (0%)	1/50 (2%) 2/50 (4	,	0/49 (0%) 0/48 (0%)
verall Incidence	Total	3/298 (1.01%)	Mean 1% SD 1.67	,	Mean 0% SD 0%
Pancreas: Carcinoma					
		0/50 (0%)	0/49 (0%) 0/49 (0		0/49 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0	,	0/49 (0%) 0/48 (0%)
verall Incidence	Total	0/298 (0%)	Mean 0% SD 0%	Total 0/245 (0%)	Mean 0% SD 0%
Pancreas: Carcinoma or Adenoma					
		0/50 (0%)	0/49 (0%) 0/49 (0	%) 0/50 (0%)	0/49 (0%)
		0/50 (0%)	1/50 (2%) 2/50 (4	%) 0/49 (0%)	0/49 (0%) 0/48 (0%)
verall Incidence	Total	3/298 (1.01%)	Mean 1% SD 1.67	,	Mean 0% SD 0%
Pancreas: Mixed Tumor Benign					
•		1/50 (2%)	0/49 (0%) 0/49 (0	%) 0/50 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0	%) 0/49 (0%)	0/49 (0%) 0/48 (0%)
verall Incidence	Total	1/298 (0.34%)	Mean 0.33% SD 0.82		Mean 0% SD 0%
Pancreas: Mixed Tumor Malignant					2/2
		0/50 (0%)	0/49 (0%) 0/49 (0		0/49 (0%)
N	T-1-1	1/50 (2%)	0/50 (0%) 0/50 (0	,	0/49 (0%) 0/48 (0%)
Overall Incidence	Total	1/298 (0.34%)	Mean 0.33% SD 0.82	2% Total 0/245 (0%)	Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 221 Report Date:11/17/2008

			Male				Female	
Parathyroid Gland: Adenoma								
		0/49 (0%)		/46 (2%)		0/47 (0%)	0/48 (0%)	
		0/49 (0%)	` '	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	3/287 (1.05%)	Mean 1.08%	SD 1.18%	Total	0/243 (0%)	Mean 0%	SD 0%
Peripheral Nerve: Schwannoma Malignant								
_		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	` ')/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Peripheral Nerve: Schwannoma: Benign, Mal	ignant, NOS	3						
		0/50 (0%)	` ,)/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	` ')/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Distalis Adenoma								
		10/50 (20%)	` ,	20/50 (40%)		17/50 (34%)	24/49 (49%)	
		8/50 (16%)	` ,	13/50 (26%)		25/50 (50%)	29/48 (60%)	20/50 (40%)
verall Incidence	Total	77/299 (25.75%)	Mean 25.78%	SD 9.08%	Total	115/247 (46.56%)	Mean 46.68%	SD 10.13%
Pituitary Gland: Pars Distalis Carcinoma								
		0/50 (0%)		0/50 (0%)		0/50 (0%)	1/49 (2%)	(05:)
		0/50 (0%)	` '	0/50 (0%)		0/50 (0%)	0/48 (0%)	1/50 (2%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	2/247 (0.81%)	Mean 0.81%	SD 1.11%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Vehicle: FEED

Route: ORAL

Length of Study: CHRONIC

Male Female *Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma 10/50 (20%)10/50 (20%)20/50 (40%)(34%)(51%)8/50 (16%)16/49 (33%)13/50 (26%)25/50 (50%)29/48 (60%)21/50 (42%) 77/299 (25.75%) **Overall Incidence** Total Mean 25.78% SD 9.08% 117/247 (47.37%) Mean 47.49% SD 9.97% Total *Pituitary Gland: Pars Intermedia: Adenoma 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/49 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/48 (0%)0/50 (0%)**Overall Incidence** Mean 0.33% SD 0.82% 0/247 (0%) SD 0% Total 1/299 (0.33%) Total Mean 0% *Pituitary Gland: Pars Intermedia: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)(0%)0/50 (0%) 0/50 (0%)0/48 (0%)0/50 (0%)**Overall Incidence** SD 0% SD 0% Total 0/299 (0%) Mean 0% Total 0/247 (0%) Mean 0% *Pituitary Gland: Pars Intermedia: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)1/50 (2%)0/49 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/48 (0%)0/50 (0%)**Overall Incidence** 1/299 (0.33%) SD 0.82% SD 0% Total Mean 0.33% Total 0/247 (0%) Mean 0% *Prostate: Adenoma

0/50

0/50

.....

(0%)

(0%)

SD 0.82%

Total

0/49

1/50

1/299

(0%)

(2%)

(0.33%)

0/50

0/50

(0%)

(0%)

Mean 0.33%

Overall Incidence

Page: 222

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 223

			Male				Female	
*Prostate: Carcinoma or Adenoma								
		0/49 (0%)	0/50 (0%)	0/50 (0%)				
	-	1/50 (2%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%				
*Salivary Glands: Sarcoma								
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
Occupation at damps	T-1-1	0/50 (0%)	0/50 (0%)	0/48 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/296 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
*Salivary Glands: Schwannoma Malignant								
_		1/49 (2%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/296 (0.34%)	Mean 0.34%	SD 0.83%	Total	0/250 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma			•••••					
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Hemangioma								
9		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 224

			Male				Female	
Skeletal Muscle: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	- / / /
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	2 (22 (22 (22 (22 (22 (22 (22 (22 (22 (
	+	0/50 (0%)	0/50 (0%)	0/50 (0%)	+	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Rhabdomyosarcoma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Rhabdomyosarcoma or	Rhahdomyom	a	•••••			•••••		
Kilabaomyosarcoma or	Kilabaolilyolil	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Sarcoma					•••••			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 225

			Male				Female	
#Skin: Basal Cell Adenoma								
		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.03%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
	TOLAI	2/300 (0.67%)	ivicali 0.07 /6	3D 1.03%	ı olal	0/230 (0/%)	ivieaii 076	30 0%
Skin:	Pacacauamau	a Tumor Ponian						
Basal Cell Adenoma or I	basosquamou	0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	` ,	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/250 (0%)	Mean 0%	SD 0%
Skin: Basal Cell Adenoma, Ba Trichoepithelioma Overall Incidence	sosquamous [·] Total	0/50 (0%) 0/50 (0%)	` ,	0/50 (0%) 0/50 (0%) SD 1.03%	Total	0/50 (0%) 1/50 (2%)	0/50 (0%) 1/50 (2%) Mean 0.8%	0/50 (0%) SD 1.1%
	Total	2/300 (0.67%)	wean 0.67%	SD 1.03%	TOTAL	2/250 (0.8%)		۱.۱% ط۶
Skin: Basal Cell Carcinoma								
		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	0.450 (004)
		0/50 (0%)	` ,	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%
≠Skin: Basal Cell Carcinoma or NOS)	· Basosquamo	us Tumor (malignant o	r					
-,		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	
	Total	0/50 (0%) 1/300 (0.33%)	` '	1/50 (2%) SD 0.82%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Overall Incidence			Mean 0.33%					

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/17/2008

Page: 226

Species: RATS Strain: F344 Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
Skin: Basal Cell Carcinoma, Tumor (benign, malign		Trichoepithelioma 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/50 (0%) 3/300 (1%)	1/50 (2%) Mean 1%	1/50 (2%) SD 1.1%	Total	1/50 (2%) 2/250 (0.8%)	1/50 (2%) Mean 0.8%	0/50 (0%) SD 1.1%
Skin: Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan	oma, Adenoma,	Papilloma, Sq pithelioma 11/50 (22%)	4/50 (8%)	1/50 (2%)		3/50 (6%)	0/50 (0%)	
Overall Incidence	Total	2/50 (4%) 27/300 (9%)	3/50 (6%) Mean 9%	6/50 (12%) SD 7.24%	Total	1/50 (2%) 7/250 (2.8%)	2/50 (4%) Mean 2.8%	1/50 (2%) SD 2.28%
		217300 (370)	Wican 570	OD 1.2470		17200 (2.070)	WCarr 2.070	OD 2.2070
Skin: Fibroma		E/EQ (400V)	4/50 (00/)	4/50 (00/)		2/50 (00/)	0/50 (0%)	
		5/50 (10%) 5/50 (10%)	4/50 (8%) 8/50 (16%)	1/50 (2%) 3/50 (6%)		3/50 (6%) 1/50 (2%)	0/50 (0%) 1/50 (2%)	1/50 (2%)
verall Incidence	Total	26/300 (8.67%)	Mean 8.67%	SD 4.68%	Total	6/250 (2.4%)	Mean 2.4%	SD 2.19%
Skin: Fibroma, Fibrosarcom Fibrous Histiocytoma	a, Sarcoma, My	xoma, Myxosarcoma, or	4/50 (8%)	4/50 (8%)		4/50 (8%)	0/50 (0%)	
		5/50 (10%)	8/50 (16%)	4/50 (8%)		3/50 (6%)	1/50 (2%)	1/50 (2%)
verall Incidence	Total	31/300 (10.33%)	Mean 10.33%	SD 3.2%	Total	9/250 (3.6%)	Mean 3.6%	SD 3.29%
Skin: Fibrosarcoma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	2/50 (4%) 0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (20/)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		U/SU (U%)	U/SU (U%)	1/50 (2%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Male Female #Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma (2%)(6%)(0%)0/50 (0%)0/50 (0%)1/50 (2%)2/50 (4%)0/50 (0%)1/50 (2%)SD 2.34% Mean 1.6% SD 1.67% Overall Incidence Total 5/300 (1.67%) Mean 1.67% Total 4/250 (1.6%) #Skin: **Fibrous Histiocytoma** 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)SD 0.82% SD 0% **Overall Incidence** Total 1/300 (0.33%) Mean 0.33% Total 0/250 (0%) Mean 0% #Skin: Hemangioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% 0/250 (0%) Mean 0% SD 0% Total #Skin: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)(0%)0/50 0/50 (0%)0/50 0/50 (0%)SD 0% SD 0% **Overall Incidence** Total 0/300 (0%) Mean 0% Total 0/250 (0%) Mean 0% #Skin: Keratoacanthoma 10/50 (20%)3/50 1/50 (2%)(6%)0/50 (0%)(0%)2/50 (4%)1/50 (2%)4/50 (8%) 0/50 (0%)0/50 0/50 (0%)**Overall Incidence** Total 21/300 (7%) Mean 7% SD 6.78% Total 3/250 (1.2%) Mean 1.2% SD 2.68%

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Page: 227

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 228
Report Date:11/17/2008

Species: RATS Strain: F344 Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male	Female
Skin:				
Lipoma		0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
		1/50 (2%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
verall Incidence	Total	3/300 (1%)	Mean 1% SD 1.1%	Total 0/250 (0%) Mean 0% SD 0%
 Skin:				
Liposarcoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Novell Incidence	Total	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/250 (0%) Maan 0% SD 0%
verall Incidence	Total	0/300 (0%)	Mean 0% SD 0%	Total 0/250 (0%) Mean 0% SD 0%
Skin: Neural Crest Tumor				
riodiai oroot ramoi		0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%) 0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33% SD 0.82%	Total 1/250 (0.4%) Mean 0.4% SD 0.89%
Skin:	••••••			
Neural Crest Tumor, M	alignant	0/50 (00/)	0/50 (00/) 0/50 (00/)	0/50 (00/) 0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33% SD 0.82%	Total 0/250 (0%) Mean 0% SD 0%
		` ,		
Skin: Neurofibroma or Schw	annoma benign			
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0% SD 0%	Total 0/250 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 229
Report Date:11/17/2008

Species: RATS Strain: F344 Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
#Skin:								
Neurofibrosarcoma or So	chwannoma (i	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma, Neu malignant or NOS)	rofibroma, or	Schwannoma (benign,						
manghant of Noo,		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin: Osteosarcoma		4/50 (004)	0/50 (00/)	0(50 (00))		0(50 (004)	0/50 (00/)	
Overall Incidence	Total	1/50 (2%) 0/50 (0%) 1/300 (0.33%)	0/50 (0%) 0/50 (0%) Mean 0.33%	0/50 (0%) 0/50 (0%) SD 0.82%	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin:								
Sarcoma		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 2/300 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.03%	Total	2/50 (4%) 2/250 (0.8%)	0/50 (0%) Mean 0.8%	0/50 (0%) SD 1.79%
#Skin: Schwannoma Benign		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F344

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Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 230

			Male				Female	
#Skin: Schwannoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Skin: Squamous Cell Carcinom	 ıa							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	4/50 (00/)
verall Incidence	Total	0/50 (0%) 2/300 (0.67%)	1/50 (2%) Mean 0.67%	1/50 (2%) SD 1.03%	Total	0/50 (0%) 1/250 (0.4%)	0/50 (0%) Mean 0.4%	1/50 (2%) SD 0.89%
verall incluence	Total	2/300 (0.67%)	Weatt 0.07%	3D 1.03%	TOtal	1/230 (0.4%)	Wealt 0.4%	3D 0.09%
Squamous Cell Carcinom Basosquamous Tumor (m verall Incidence			0/50 (0%) 1/50 (2%) Mean 1%	0/50 (0%) 2/50 (4%) SD 1.67%	Tatal	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
		3/300 (1%)	Wican 170		Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
		······			i otal			SD 0.69%
Skin: Squamous Cell Papilloma	a	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Skin: Squamous Cell Papilloma		1/50 (2%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	
Skin: Squamous Cell Papilloma overall Incidence	a Total	1/50 (2%) 0/50 (0%) 2/300 (0.67%)	0/50 (0%) 0/50 (0%) Mean 0.67%	0/50 (0%) 1/50 (2%) SD 1.03%		0/50 (0%) 0/50 (0%) 1/250 (0.4%)	0/50 (0%) 1/50 (2%) Mean 0.4%	0/50 (0%)
Skin: Squamous Cell Papilloma Overall Incidence Skin:	a Total	1/50 (2%) 0/50 (0%) 2/300 (0.67%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

ed Control Animal Groups

Page: 231

Report Date:11/17/2008

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Skin: Squamous Cell Papillo Carcinoma or Keratoac		Squamous Cell						
		11/50 (22%)	3/50 (6%)	1/50 (2%)		3/50 (6%)	0/50 (0%)	4/50 (00/)
Overall Incidence	Total	2/50 (4%) 25/300 (8.33%)	2/50 (4%) Mean 8.33%	6/50 (12%) SD 7.53%	Total	0/50 (0%) 5/250 (2%)	1/50 (2%) Mean 2%	1/50 (2%) SD 2.45%
#Skin:								
Squamous Cell Papillo	ma, Papilloma,	or Keratoacanthoma 11/50 (22%) 2/50 (4%)	3/50 (6%) 1/50 (2%)	1/50 (2%) 5/50 (10%)		3/50 (6%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	23/300 (7.67%)	Mean 7.67%	SD 7.63%	Total	4/250 (1.6%)	Mean 1.6%	SD 2.61%
#Skin: Trichoepithelioma	•••••							
•		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%
#Skin: Sebaceous Gland: Adenoma	•••••	(201)	(00)	0.50			(201)	
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/17/2008

Page: 232

Species: RATS Strain: F344

Length of Study: CHRONIC

Route: ORAL Vehicle: FEED

			Male				Female	
#Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0.50
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Spinal Cord: Astrocytoma Benign								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
Our well by all laws a	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Spinal Cord: Astrocytoma Malignant								
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Spinal Cord: Glioma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Spleen: Fibrosarcoma		0/50 (00/)	0/50 (00/)	0/40 (00/)		0/40 (00/)	0/50 (00/)	
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
TVEI all illuluellue	TULAI	0/290 (0%)	IVICALI U70	SD 0%	i Ulai	0/24/ (0%)	IVICALI U70	3D 0%

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 233

			Male		Female	
Spleen: Fibrous Histiocytoma						
r izrodo monocytoma		0/50 (0%)	0/50 (0%) 0/49	(0%)	0/49 (0%) 0/50 (0%)	
		1/49 (2%)	0/50 (0%) 0/50	(0%)	0/49 (0%) 0/50 (0%)	0/49 (0%)
verall Incidence	Total	1/298 (0.34%)		0.83% Total	0/247 (0%) Mean 0%	SD 0%
Spleen: Hemangioma						
_		0/50 (0%)	0/50 (0%) 0/49	(0%)	0/49 (0%) 0/50 (0%)	0/40 (00/)
		0/49 (0%)	0/50 (0%) 0/50	(0%)	0/49 (0%) 0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/298 (0%)	Mean 0% SD	0% Total	0/247 (0%) Mean 0%	SD 0%
Spleen: Hemangiosarcoma						
•		0/50 (0%)	1/50 (2%) 0/49	(0%)	0/49 (0%) 0/50 (0%)	
		0/49 (0%)	0/50 (0%) 0/50	(0%)	0/49 (0%) 0/50 (0%)	0/49 (0%)
verall Incidence	Total	1/298 (0.34%)		0.82% Total	0/247 (0%) Mean 0%	SD 0%
Spleen: Leiomyosarcoma						
•		0/50 (0%)	1/50 (2%) 0/49	(0%)	0/49 (0%) 0/50 (0%)	
		0/49 (0%)	0/50 (0%) 0/50	(0%)	0/49 (0%) 0/50 (0%)	0/49 (0%)
verall Incidence	Total	1/298 (0.34%)	Mean 0.33% SD	0.82% Total	0/247 (0%) Mean 0%	SD 0%
Spleen: Sarcoma						
		0/50 (0%)	0/50 (0%) 0/49	(0%)	0/49 (0%) 0/50 (0%)	0/40 (00%)
Normall In all Inner	T-1-1	0/49 (0%)	0/50 (0%) 0/50	(0%)	0/49 (0%) 0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0% SD	0% Total	0/247 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

47 1 411

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 234

			Male		Female	
Stomach, Forestomach: Leiomyosarcoma						
•		0/50 (0%)	0/50 (0%) 1/5	- ()	0/50 (0%) 0/50 (0%)	
Normall In all Invan	T-1-1	0/50 (0%)	0/50 (0%) 0/5	` '	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82% Total	l 0/250 (0%) Mean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma						
-		0/50 (0%)	0/50 (0%) 0/5		0/50 (0%) 0/50 (0%)	2 (22 (22 (22 (22 (22 (22 (22 (22 (22 (
		0/50 (0%)	0/50 (0%) 0/5	` '	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0% Total	I 0/250 (0%) Mean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma c	or Papillon	na Squamous 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/5 0/50 (0%) 0/5	` ,	0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	` /	SD 0% Total	, , , , , , , , , , , , , , , , , , , ,	SD 0.89%
Stomach, Forestomach: Squamous Cell Papilloma						
		0/50 (0%)	0/50 (0%) 0/5	` ,	0/50 (0%) 0/50 (0%)	0/50 (00/)
	-	0/50 (0%)	0/50 (0%) 0/5	` '	1/50 (2%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)		SD 0% Total		SD 0.89%
Stomach, Glandular: Leiomyosarcoma						
		0/50 (0%)	0/50 (0%) 0/5	- ()	0/50 (0%) 0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/50 (0%)	0/50 (0%) 0/5	` '	0/50 (0%) 0/50 (0%) I 0/250 (0%) Mean 0%	0/50 (0%)
	LOtal	0/300 (0%)	Mean 0%	SD 0% Total	1 1/250 //10/1 N/1000 /10/	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/17/2008

Page: 235

Species: RATS Strain: F344 Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
#Stomach, Glandular: Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		, ,				` ,		
*Testes: Adenoma								
		45/50 (90%)	46/50 (92%)	49/50 (98%)				
Overall Incidence	Total	42/50 (84%) 274/300 (91.33%)	46/50 (92%) Mean 91.33%	46/50 (92%) SD 4.5%				
Overall molacines		,						
*Thymus: Sarcoma								
		0/48 (0%)	0/48 (0%)	0/47 (0%)		0/50 (0%)	0/46 (0%)	
O	T-1-1	0/48 (0%)	0/48 (0%)	0/41 (0%)	T-1-1	0/49 (0%)	0/47 (0%)	0/50 (0%)
Overall Incidence	Total	0/280 (0%)	Mean 0%	SD 0%	Total	0/242 (0%)	Mean 0%	SD 0%
*Thymus:		•••••						•••••
Thymoma Benign		0/48 (0%)	0/48 (0%)	0/47 (0%)		0/50 (0%)	0/46 (0%)	
		1/48 (2%)	0/48 (0%)	0/41 (0%)		0/49 (0%)	0/47 (0%)	0/50 (0%)
Overall Incidence	Total	1/280 (0.36%)	Mean 0.35%	SD 0.85%	Total	0/242 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant								
		0/48 (0%) 0/48 (0%)	0/48 (0%) 0/48 (0%)	0/47 (0%) 0/41 (0%)		0/50 (0%) 0/49 (0%)	0/46 (0%) 0/47 (0%)	0/50 (0%)
Overall Incidence	Total	()	` '	` '	Total	` ,	` '	` ,
Overall Incidence	Total	0/280 (0%)	Mean 0%	SD 0%	Total	0/242 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 236

			Male				Female	
Thymus:								
Thymoma: Benign, Malignan	it, NOS	0/40 (00/)	0/40 /00/)	0/47 (00/)		0/50 (00/)	0/46 (00/)	
		0/48 (0%) 1/48 (2%)	0/48 (0%) 0/48 (0%)	0/47 (0%) 0/41 (0%)		0/50 (0%) 0/49 (0%)	0/46 (0%) 0/47 (0%)	0/50 (0%)
Overall Incidence	Total	1/280 (0.36%)	Mean 0.35%	SD 0.85%	Total	0/49 (0%)	Mean 0%	SD 0%
verali ilicidence		,				,		
Thyroid Gland: C-Cell: Adenoma								
		10/50 (20%)	5/50 (10%)	6/50 (12%)		4/50 (8%)	3/49 (6%)	
		7/50 (14%)	11/47 (23%)	5/48 (10%)		4/50 (8%)	10/47 (21%)	2/47 (4%)
Overall Incidence	Total	44/295 (14.92%)	Mean 14.97%	SD 5.51%	Total	23/243 (9.47%)	Mean 9.53%	SD 6.75%
Thyroid Gland: C-Cell: Carcinoma		1/50 (2%) 1/50 (2%)	4/50 (8%) 0/47 (0%)	1/50 (2%) 1/48 (2%)	T . /	0/50 (0%) 1/50 (2%)	1/49 (2%) 1/47 (2%)	0/47 (0%)
Overall Incidence	Total	8/295 (2.71%)	Mean 2.68%	SD 2.73%	Total	3/243 (1.23%)	Mean 1.23%	SD 1.13%
Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		11/50 (22%)	9/50 (18%)	7/50 (14%)		4/50 (8%)	4/49 (8%)	
		8/50 (16%)	11/47 (23%)	6/48 (13%)		5/50 (10%)	11/47 (23%)	2/47 (4%)
Overall Incidence	Total	52/295 (17.63%)	Mean 17.65%	SD 4.35%	Total	26/243 (10.7%)	Mean 10.76%	SD 7.37%
Thyroid Gland: Follicular Cell: Adenoma								
		2/50 (4%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	
		0/50 (0%)	0/47 (0%)	0/48 (0%)		0/50 (0%)	2/47 (4%)	0/47 (0%)
Overall Incidence	Total	4/295 (1.36%)	Mean 1.33%	SD 2.07%	Total	2/243 (0.82%)	Mean 0.85%	SD 1.9%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Page: 237

Report Date:11/17/2008

Strain: F344
Length of Study: CHRONIC

Male

			Male			Female
*Thyroid Gland: Follicular Cell: Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/50 (0%) 0/295 (0%)	0/47 (0%) Mean 0%	0/48 (0%) SD 0%	0/50 (0%) Total 1/243 (0.41%)	0/47 (0%) 1/47 (2%) Mean 0.43% SD 0.95%
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma						
		2/50 (4%) 0/50 (0%)	2/50 (4%) 0/47 (0%)	0/50 (0%) 0/48 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 2/47 (4%) 1/47 (2%)
Overall Incidence	Total	4/295 (1.36%)	Mean 1.33%	SD 2.07%	Total 3/243 (1.23%)	Mean 1.28% SD 1.9%
#Tissue NOS: Lipoma						
·		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total 0/250 (0%)	Mean 0% SD 0%
#Tissue NOS:	•••••					
Paraganglioma		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/300 (0.33%)	0/50 (0%) Mean 0.33%	1/50 (2%) SD 0.82%	0/50 (0%) Total 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
#Tissue NOS: Schwannoma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%) 0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total 1/250 (0.4%)	Mean 0.4% SD 0.89%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 238

			Male		Female	
Tongue:						
Squamous Cell Carcinoma		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0% SD (` '	0/250 (0%) Mean 0%	SD 0%
······································						
Squamous Cell Carcinoma	or Papillon	na Squamous				
		1/50 (2%)	1/50 (2%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0.000 (0.000)
		1/50 (2%)	0/50 (0%) 1/50	(2%)	1/50 (2%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	4/300 (1.33%)	Mean 1.33% SD	.03% Total	1/250 (0.4%) Mean 0.4%	% SD 0.89%
Tongue: Squamous Cell Papilloma		•••••				•••••
- 4		1/50 (2%)	1/50 (2%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	
		1/50 (2%)	0/50 (0%) 1/50	(2%)	1/50 (2%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	4/300 (1.33%)	Mean 1.33% SD 7	.03% Total	1/250 (0.4%) Mean 0.4%	6 SD 0.89%
Tooth:		•••••				
Adamantinoma Malignant		2/22 (22/)	2/22 (221)	(00()	0/50 (00/)	
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (00/)
Averall Inclidence	Tatal	0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0% SD (0/250 (0%) Mean 0%	SD 0%
Tooth: Odontoma						
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0% SD ()% Total	0/250 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 239

			Male		Fema	le
*Urinary Bladder: Carcinoma						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 0/49 (0%) 0/50	(0%) (0%)	0/50 (0%) 0/50 0/50 (0%) 0/49	(0%) (0%) 0/50 (0%)
Overall Incidence	Total	0/298 (0%)	,	0% Total	0/249 (0%) Mean	` '
*Urinary Bladder: Carcinoma or Papilloma						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/49 0/49 (0%) 0/50	(2%) (0%)	0/50 (0%) 0/50 0/50 (0%) 0/49	(0%) (0%) 0/50 (0%)
Overall Incidence	Total	1/298 (0.34%)	` ,	0.83% Total	0/249 (0%) Mean	` '
*Urinary Bladder: Leiomyosarcoma						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 0/49 (0%) 0/50	(0%) (0%)	0/50 (0%) 0/50 0/50 (0%) 0/49	(0%) (0%) 0/50 (0%)
Overall Incidence	Total	0/30 (0%)	, ,	0% Total	0/249 (0%) Mean	` '
*Urinary Bladder: Papilloma						
		0/50 (0%)	0/50 (0%) 1/49	(2%)		(0%)
Overall Incidence	Total	0/50 (0%) 1/298 (0.34%)	0/49 (0%) 0/50 Mean 0.34% SD	(0%) 0.83% Total	0/50 (0%) 0/49 0/249 (0%) Mean	(0%) 0/50 (0%) 0% SD 0%
#Uterus: Adenoma						
, asilolila					0/50 (0%) 0/50 0/50 (0%) 0/50	(0%) (0%) 1/50 (2%)
Overall Incidence				Total	` ,	(0%) 1/50 (2%) 0.4% SD 0.89%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 240

Report Date:11/17/2008

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male	Female	
#Uterus: Carcinoma Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/250 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Deciduoma Benign			
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/250 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Hemangioma		0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/250 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Hemangiosarcoma			
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/250 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Leiomyoma		0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/250 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 241

		Female			
Jterus:					
Leiomyosarcoma			0/50 (0%)	0/50 (0%)	
			0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
verall Incidence		Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Jterus:					
Polyp Stromal			6/50 (12%)	10/50 (20%)	
			14/50 (28%)	16/50 (32%)	10/50 (20%)
verall Incidence		Total	56/250 (22.4%)	Mean 22.4%	SD 7.8%
Jterus:					
Sarcoma Stromal			0/50 (00/)	0/50 (00/)	
			0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
verall Incidence		Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Jterus:					
Sarcoma Stromal or Polyp Stromal			6/50 (12%)	10/50 (20%)	
			14/50 (28%)	17/50 (34%)	10/50 (20%)
verall Incidence		Total	57/250 (22.8%)	Mean 22.8%	SD 8.44%
Jterus:					
Schwannoma Malignant					
			0/50 (0%)	0/50 (0%)	0/50 (00/)
verall Incidence		Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
veran incluence		Total	0/200 (0%)	ivieai1 0%	3D 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

ontrol Animal Groups Report Date:11/17/2008

Page: 242

			Male				Female	
#Vagina: Polyp						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Vagina: Sarcoma	•••••					0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Zymbal's Gland: Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Zymbal's Gland: Carcinoma		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/50 (0%) 4/300 (1.33%)	3/50 (6%) Mean 1.33%	0/50 (0%) SD 2.42%	Total	0/50 (0%) 1/250 (0.4%)	0/50 (0%) Mean 0.4%	0/50 (0%) SD 0.89%
#Zymbal's Gland: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/50 (0%) 4/300 (1.33%)	3/50 (6%) Mean 1.33%	0/50 (0%) SD 2.42%	Total	0/50 (0%) 1/250 (0.4%)	0/50 (0%) Mean 0.4%	0/50 (0%) SD 0.89%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied